IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	CIVIL ACTION
Plaintiff	:	
	:	
vs.	:	
	:	
ASTRAZENECA PHARMACEUTICALS LP, *et al.*,	:	
Defendants.	:	NO. 08cv4786

MEMORANDUM

YOHN, J. October __, 2010

Plaintiff, Teva Pharmaceutical Industries Ltd. ("Teva"), sues AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc. (collectively "AstraZeneca"), for patent infringement, alleging that AstraZeneca's CRESTOR® prescription drug products infringe one or more claims of Teva's U.S. Patent No. RE39,502 ("the '502 patent").[1] According to Teva, the '502 patent, entitled "Stable Pharmaceutical Compositions Containing 7–Substituted–3,5–Dihydroxyheptanoic Acids or 7–Substituted–3,5–Dihydroxyheptenoic Acids," claims "stabilized pharmaceutical compositions comprising statins for the treatment of dyslipidemia." (Compl. ¶ 12.) In particular, the '502 patent discloses "stabilized pharmaceutical compositions comprising statins formulated with certain excipients[,] [namely, amido-group containing polymeric compounds,] that prevent degradation of the statins over time." (*Id.*)

AstraZeneca has filed a motion for summary judgment of patent invalidity due to prior invention pursuant to 35 U.S.C. § 102(g)(2). Although AstraZeneca in fact disputes that its

[1] Teva originally sued two additional defendants: AstraZeneca PLC and AstraZeneca UK Limited. Pursuant to a June 4, 2009, Joint Stipulation of Dismissal, however, those entities are no longer parties to this action.

CRESTOR® products infringe the asserted claims of Teva's '502 patent, AstraZeneca concedes—for purposes of the instant motion only—that the accused CRESTOR® product formulations fall within the scope of those claims.[2] AstraZeneca argues that if the accused products infringe, as Teva alleges, then the asserted '502 patent claims are invalid because AstraZeneca "made," *i.e.*, conceived of and reduced to practice, the drug formulations that are now sold as CRESTOR® before Teva invented the subject matter of the '502 patent, and because AstraZeneca has not abandoned, suppressed, or concealed those formulations. Teva opposes the motion, arguing that even if AstraZeneca made the infringing products first, AstraZeneca has not shown prior invention of the subject matter of the '502 patent because there is no evidence that AstraZeneca has ever appreciated that crospovidone, the amido-group containing polymeric compound included in CRESTOR®, contributes to the stability of the formulation, a critical appreciation in Teva's view.

As set forth herein, the court concludes that AstraZeneca was not required to have such a particularized appreciation in order to prove prior conception and reduction to practice of the invention claimed by Teva. Accordingly, because it is undisputed that (1) AstraZeneca made the accused product formulations before Teva invented the subject matter of the asserted claims, (2) appreciated that the formulations were stable, and (3) did not abandon, suppress, or conceal the formulations, the court will grant AstraZeneca's motion for summary judgment.

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[2] The parties agree that the patent claims at issue are independent claims 1, 26, 42, and 52 of the '502 patent. (Statement of Undisputed Facts in Supp. of AstraZeneca's Mot. for Summ. J. of Patent Invalidity Due to Prior Invention ["AstraZeneca Statement"] ¶ 5; Teva Pharm. Indus. Ltd.'s Resp. to AstraZeneca's Statement of Undisputed Facts in Supp. of Their Mot. for Summ. J. of Patent Invalidity Due to Prior Invention ["Teva Resp."] ¶ 5; *see also Teva Pharm. Indus. Ltd. v. AstraZeneca Pharm. LP*, No. 08-4786, Order at 1 (Jan. 14, 2010) (noting that "[o]nly claims 1, 26, 42 and 52 are raised in the current infringement action").)

I. Facts and Procedural History[3]

A. AstraZeneca's Development of CRESTOR®

CRESTOR® is a prescription medication belonging to a group of drugs called statins that are used to treat high cholesterol. (Compl. ¶ 14; AstraZeneca Ans. ¶ 14[4]; AstraZeneca Statement ¶ 3; Teva Resp. ¶ 3.) The active pharmaceutical ingredient in CRESTOR® is rosuvastatin calcium. (Astrazeneca Statement ¶ 4; Teva Resp. ¶ 4.)

Sales of CRESTOR® products began after the FDA approved the New Drug Application ("NDA") for CRESTOR® in August 2003. (AstraZeneca Statement ¶ 23; Teva Resp. ¶ 23.) The CRESTOR® NDA lists the ingredients and the amount of each ingredient for all dosage strengths of CRESTOR® tablets that AstraZeneca sells commercially today. (*See* AstraZeneca Statement ¶ 24; Teva Resp. ¶ 24; Declaration of J. Richard Creekmore, Ph.D. ["Creekmore Decl."] ¶¶ 8-9 & Ex. A at AZ-EDPA-0019433; Decl. of Alan E. Sloan ["Sloan Decl."] ¶¶ 7-9.)[5]

AstraZeneca researchers in Wilmington, Delaware, arrived at the formulations for all

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[3] On this motion for summary judgment, the court must view the facts in the light most favorable to Teva, the non-moving party. Except where otherwise noted, the facts set forth herein are undisputed.

[4] Because the answers filed by AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc., are substantially identical, citations to "AstraZeneca Ans." refer to the answers filed by both defendants.

[5] The CRESTOR® NDA lists the ingredients and the amounts for six dosage strengths: 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg. (Creekmore Decl., Ex. A at AZ-EDPA-0019433.) Defendant IPR Pharmaceuticals, Inc. makes tablets of all but the 80 mg dosage strength in Puerto Rico. (AstraZeneca Statement ¶ 20; Teva Resp. ¶ 20.) Defendant AstraZeneca Pharmaceuticals LP sells four of the dosage strengths—the 5 mg, 10 mg, 20 mg, and 40 mg tablets—in the United States. (AstraZeneca Statement ¶ 22; Teva Resp. ¶ 22.) The 2.5 mg tablets are sold in Japan. (Sloan Decl. ¶ 7 n.1.) The 80 mg tablets are not currently marketed in any country. (*Id.*)

dosage strengths of the CRESTOR® tablet cores in 1999. (*See* AstraZeneca Statement ¶¶ 26, 42-45; Teva Resp. ¶¶ 26, 42-45.) The researchers had used different formulations for earlier Phase III clinical studies, but they wanted to improve on these earlier formulations for the final commercial product. (AstraZeneca Statement ¶ 27; Teva Resp. ¶ 27.) In particular, because the researchers already knew from the Phase III studies that rosuvastatin calcium would be safe and effective, they focused on product stability and manufacturability issues when developing the improved commercial formulations. (AstraZeneca Statement ¶ 28; Teva Resp. ¶ 28.)

Led by Richard Creekmore, the researchers began development of the planned commercial CRESTOR® products, referred to internally as the rosuvastatin "sales formulations," in early 1999.[6] (AstraZeneca Statement ¶¶ 29, 32; Teva Resp. ¶¶ 29, 32.) Shortly thereafter, AstraZeneca developed an uncoated tablet formulation containing all ingredients of the tablets cores of commercial CRESTOR® products: rosuvastatin calcium, lactose monohydrate, microcrystalline cellulose (trade name "Avicel"), tribasic calcium phosphate, crospovidone, and magnesium stearate. (AstraZeneca Statement ¶ 33; Teva Resp. ¶ 33.) Creekmore testified that at some point between the late summer of 1998 and early 1999, he had settled on tribasic calcium phosphate as a stabilizer for the product. (Declaration of Jonathan K. Waldrop ["Waldrop Decl."], Ex. 5 ["Creekmore Dep."] 206:20-24; *see also* Creekmore Decl., Ex. A at AZ-EDPA-0019432 (CRESTOR® NDA excerpt characterizing the function of tribasic calcium phosphate as "Stabilizer").) Although the formulation also included crospovidone, an amido-group containing polymeric compound, crospovidone "was included in the CRESTOR® formulations for its

[6]Precise dates are included in the parties' submissions but are kept confidential at the request of AstraZeneca. The exact dates are not essential to the analysis here.

properties as a disintegrant." (AstraZeneca Reply 2; *see also* Creekmore Dep. 251:13-20, 252:7-13; Creekmore Decl., Ex. A at AZ-EDPA-0019432 (CRESTOR® NDA excerpt characterizing the function of crospovidone as "Disintegrant").)

In mid 1999, AstraZeneca planned to make 10,000-unit batches of uncoated 2.5 mg rosuvastatin sales formulation tablets. (AstraZeneca Statement ¶ 34; Teva Resp. ¶ 34.) A week later, AstraZeneca manufactured a 10,000-unit batch of 2.5 mg rosuvastatin sales formulation tablets containing the same ingredients, in the same amounts, as the commercial 2.5 mg CRESTOR® tablet cores. (AstraZeneca Statement ¶¶ 35-36; Teva Resp. ¶¶ 35-36.) Approximately two months later, AstraZeneca manufactured a 20,000-unit batch of 5 mg rosuvastatin calcium tablets. (AstraZeneca Statement ¶ 38-39; Teva Resp. ¶ 38.) These tablets contained the same ingredients, in substantially identical amounts, as the commercial 5 mg CRESTOR® tablet cores. (AstraZeneca Statement ¶ 39.)[7]

[7] In its response to AstraZeneca's statement of undisputed facts, Teva objects that "there is not complete identity of the amounts shown" in the CRESTOR® NDA and AstraZeneca's "weigh sheet" for the summer of 1999 batch. (*See* Teva Resp. ¶ 39.) Although the ingredient amounts in the "master formula" for the summer of 1999 batch match the ingredient amounts for the 5 mg tablet cores in the CRESTOR® NDA (*compare* Creekmore Decl., Ex. A at AZ-EDPA-0019433, *with id.*, Ex. D at AZ-EDPA-0001314), the weigh sheet for the batch reflects that for two of the ingredients—"ZD4522 (calcium salt)" (AstraZeneca's internal name for rosuvastatin calcium) and microcrystalline cellulose—the actual weights used differed slightly from the master formula (*see id.*, Ex. D at AZ-EDPA-0001315). The master formula for the batch explains the potential need for an adjustment of the amount of these two ingredients as follows: "ZD4522 (calcium salt) is 96.15% ZD4522. 5.20 mg of ZD4522 (calcium salt) contains 5.00 mg ZD4522. An additional correction factor may be used to compensate for the amount of moisture present in the drug substance. The amount of Microcrystalline Cellulose may be adjusted accordingly." (*Id.* at AZ-EDPA-0001314.) The weigh sheet for the batch reflects that such a correction factor was in fact applied, resulting in a slight increase in the amount of ZD4522 (calcium salt) used and a corresponding decrease in the amount of microcrystalline cellulose. (*See id.* at AZ-EDPA-0001315; Decl. of Mark McLaughlin ["McLaughlin Decl."] ¶ 20 (stating that summer of 1999 batch consisted of ingredients and amounts listed in the master formula with correctional errors indicated on the weigh sheet).)

In the late summer of 1999, Dr. Creekmore gave a presentation regarding AstraZeneca's rosuvastatin sales formulations, in which he described the proposed commercial formulations for "ZD4522" (*i.e.*, rosuvastatin) tablet cores for each of the 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg, and 80 mg dosage strengths. (Creekmore Decl. ¶ 18 & Ex. E at AZ-EDPA-0041448; *see also* AstraZeneca Statement ¶¶ 41-43; Teva Resp. ¶¶ 41-43.) The ingredients and amounts in Dr. Creekmore's presentation are the same as those found in commercial CRESTOR® products. (AstraZeneca Statement ¶ 45; Teva Resp. ¶ 45.) Creekmore's presentation also noted that "[c]oncurrent stability studies show product will have an acceptable shelf life." (Creekmore Decl., Ex. E at AZ-EDPA-0041447; *see also* AstraZeneca Statement ¶ 46; Teva Resp. ¶ 46.)

In the fall of 1999, AstraZeneca made a 160,000-unit batch of coated 2.5 mg rosuvastatin tablets. (AstraZeneca Statement ¶ 47; Teva Resp. ¶ 47.) These tablets contained the same ingredients as commercial 2.5 mg CRESTOR® tablets in substantially identical amounts.[8] (*See* AstraZeneca Statement ¶ 47.) AstraZeneca later submitted these batch records to the FDA in connection with its Investigational New Drug Application for CRESTOR®. (AstraZeneca Statement ¶ 49; Teva Resp. ¶ 49.)

On January 26, 2000, Dr. Creekmore and Norman Wiggins filed a patent application in Great Britain on behalf of AstraZeneca AB covering their rosuvastatin formulation work. (Creekmore Decl. ¶ 22; Declaration of Rama G. Elluru ["Elluru Decl."], Ex. 6 (GB application

[8] As with the summer 1999 batch, the ingredient amounts in the master formula for the fall 1999 batch match the ingredient amounts in the CRESTOR® NDA, but the weigh sheet for the batch reflects minor adjustments to the actual amount of ZD4522 (calcium salt) and microcrystalline cellulose used. (*Compare* Creekmore Decl., Ex. A at AZ-EDPA-0019433 (NDA), *with id.*, Ex. F at AZ-EDPA-0026414 to AZ-EDPA-0026415 (batch record for fall 1999 batch).)

no. 0001621.2).) According to Dr. Creekmore, Example 3 of that application contains a full description of the 2.5 mg rosuvastatin sales formulation tablets. (Creekmore Decl. ¶ 22.) Example 3 discloses the same ingredients and, apart from decimal point differences as to two ingredients, the same ingredient amounts as the 2.5 mg rosuvastatin sales formulation tablet cores that AstraZeneca made in May and October 1999, and as the 2.5 mg commercial CRESTOR® product tablet cores.[9] (*Compare* Elluru Decl., Ex. 6 at 6 (Example 3 of GB application no. 0001621.2), *with* Creekmore Decl, Ex. C at AZ-EDPA-0001351 (weigh sheet for mid 1999 batch), *id.*, Ex. F at AZ-EDPA-0026414 (master formula for fall 1999 batch), *and id.*, Ex. A at AZ-EDPA-0019433 (NDA).)

AstraZeneca thereafter filed a patent application in the United States on August 4, 2000, which issued as U.S. Patent No. 6,316,460 ("the '460 patent") on November 13, 2001.[10] (Creekmore Decl. ¶ 23; Elluru Decl., Ex. 2 ('460 patent).) Example 3 of the '460 patent is identical to Example 3 of the Great Britain patent application. (*Compare* Elluru Decl., Ex. 2 at

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[9] As to two ingredients—microcrystalline cellulose and lactose monohydrate—Example 3 lists the amount to the tenth of a milligram, while the mid 1999 and fall 1999 batch records and the CRESTOR® NDA list the amount to the hundredth of a milligram. (*Compare* Elluru Decl., Ex. 6 at 6 (Example 3, listing ingredient amounts as 15.5 mg and 46.5 mg, respectively), *with, e.g.*, Creekmore Decl., Ex. A at AZ-EDPA-0019433 (NDA, listing ingredient amounts as 15.51 mg and 46.54, respectively).)

[10] AstraZeneca asserts that the Great Britain patent application "forms the basis of AstraZeneca's '460 patent," noting that the '460 patent references the Great Britain application under "Foreign Application Priority Data." (AstraZeneca Statement ¶ 53; Elluru Decl., Ex. 2 ('460 patent).) Teva argues that to the extent that AstraZeneca seeks to establish priority of invention by claiming that the '460 patent has an effective filing date of January 26, 2000, the filing date of the Great Britain application, it cannot do so because the Great Britain application was never published as required by 35 U.S.C. § 102(a). (*See* Teva Opp'n 12-13.) Because this contention is irrelevant to whether AstraZeneca has established priority of invention under 35 U.S.C. § 102(g), the court need not address it.

col.5 ll.14-23, *with id.*, Ex. 6 at 6.) Thus, apart from the rounding differences described in n.8 *supra*, Example 3 of the '460 patent discloses the same ingredients, in the same amounts, as the 2.5 mg rosuvastatin sales formulation tablets that AstraZeneca made in mid 1999 and fall 1999, and as the 2.5 mg commercial CRESTOR® products. (*Compare* Elluru Decl., Ex. 2 at col.5 ll.14-23, *with* Creekmore Decl., Ex. C at AZ-EDPA-0001351 (weigh sheet for mid 1999 batch), *id.*, Ex. F at AZ-EDPA-0026414 (master formula for fall 1999 batch), *and id.*, Ex. A at AZ-EDPA-0019433 (NDA).) In January 2001, while the United States patent application was pending, the Great Britain patent application was terminated. (Declaration of Darcy L. Jones ["Jones Decl."] ¶ 6 & Ex. I.)

According to Teva's expert, Harold B. Hopfenberg, Ph.D., the use of amido-group containing polymeric compounds to stabilize statin-containing pharmaceutical formulations is not disclosed in the patent application that AstraZeneca filed in Great Britain, the '460 patent, or the CRESTOR® NDA. (Decl. of Harold B. Hopfenberg ["Hopfenberg Decl."] ¶¶ 11, 14.) Although these documents do disclose certain amido-group containing polymeric compounds—including crospovidone—as excipients that can be used in the claimed formulations, such compounds are disclosed for use for purposes other than stabilization. (*See id.* ¶¶ 15, 17.) All three documents disclose the use of a separate set of compounds—namely "tribasic phosphate salts in which the cation is multivalent"[11]—for stabilization. (Hopfenberg Decl. ¶¶ 13, 18.)

B. Teva's '502 Patent

[11] Tribasic calcium phosphate, the ingredient in CRESTOR® that AstraZeneca identifies as a stabilizer, is one example of a "tribasic phosphate salt in which the cation is multivalent." (*See id.* ¶ 18; Elluru Decl., Ex. 2 ('460 patent) at col.2 ll.7-9.)

At some point prior to December 1, 1999, Teva researchers, led by Michael Fox, were working on the problem of stabilizing formulations containing pravastatin, a statin drug and a very unstable substance. (Declaration of Michael Fox ["Fox Decl."] ¶ 5.) The particular problem, according to Fox, was to prevent the transfer of hydrogen ions and resulting degradation of pravastatin. (*Id.*) In an effort to evaluate the stabilizing effect of amido-group containing polymeric compounds on formulations containing statin drugs, on approximately December 1, 1999,[12] Fox prepared 3,000 tablets of a pharmaceutical formulation containing pravastatin sodium, crospovidone, and magnesium stearate. (*Id.* ¶¶ 4-5.) As a result of this work, the Teva researchers learned that amido-group containing polymeric compounds, including crospovidone, function as a "trap" for positive ions and are therefore effective stabilizers for preparations containing statins. (*Id.* ¶ 5.) Teva thereafter performed stability tests on the December 1, 1999, formulation and confirmed that it was exceptionally stable, despite the absence of other, traditional stabilizers. (*Id.*) Teva has submitted no evidence that it conceived of or reduced to practice its invention prior to December 1, 1999.

Teva filed a provisional patent application with the United States Patent and Trademark Office ("PTO") disclosing this invention on April 10, 2000. (Waldrop Decl., Ex. 1 ('502 patent).) Teva thereafter filed a patent application concerning the invention on April 9, 2001, which issued as U.S. Patent No. 6,558,659 ("the '659 patent") on May 6, 2003. (*See id.*) Teva later filed an application for reissue of the '659 patent on March 17, 2005, which reissued as the '502 patent on March 6, 2007. (*See id.*; Teva Opp'n 12.) According to Teva, the '502 patent, entitled "Stable Pharmaceutical Compositions Containing 7–Substituted–3,5–

[12]This is approximately two months after the fall 1999 batch made by AstraZeneca.

Dihydroxyheptanoic Acids or 7–Substituted–3,5–Dihydroxyheptenoic Acids," claims "stabilized pharmaceutical compositions comprising statins for the treatment of dyslipidemia." (Compl. ¶ 12; *see also* Waldrop Decl., Ex. 1 ('502 patent).) In addition, the complaint alleges that the '502 patent "discloses stabilized pharmaceutical compositions comprising statins formulated with certain excipients[,] [namely, amido-group containing polymeric compounds,] that prevent degradation of the statins over time." (Compl. ¶ 12; *see also* Waldrop Decl., Ex. 1.)

C. Procedural History

Teva filed its complaint in this action in October 2008, alleging that AstraZeneca's manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of its CRESTOR® products infringes one or more claims of the '502 patent. (Compl. ¶ 18.) In its answer, AstraZeneca denied Teva's allegations of infringement and raised affirmative defenses of noninfringement and invalidity of Teva's '502 patent, among others. (AstraZeneca Ans. ¶¶ 18, 21, 23.)[13] AstraZeneca also asserted counterclaims for a declaratory judgment of noninfringement and a declaratory judgment of invalidity of the '502 patent. (*Id.*, Counterclaims I & II.) In April 2009 AstraZeneca moved to transfer venue to the United States District Court for the District of Delaware, which motion the court denied in August 2009.

On September 10, 2009, approximately three weeks before the original fact discovery cutoff, AstraZeneca filed the instant motion for summary judgment of patent invalidity due to prior invention. Teva thereafter sought to stay the litigation pending the outcome of reissue proceedings it had initiated by filing an application for reissue of the '502 patent with the PTO on

[13] As noted, AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc., answered the complaint separately. The remaining defendants, who are no longer parties to this action, filed motions to dismiss for lack of jurisdiction.

September 18, 2009. AstraZeneca opposed the stay, and the court denied Teva's stay motion on January 14, 2010. The parties thereafter completed the briefing of AstraZeneca's motion for summary judgment, with Teva filing its opposition on February 12, 2010, and AstraZeneca filing a reply brief on March 2, 2010. The court held oral argument in the case on June 21, 2010, and September 27, 2010.

II. Applicable Legal Standards

A motion for summary judgment should be granted "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). Material facts are facts that "might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual issue is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Id.*

In evaluating a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in [the non-movant's] favor." *Id.* at 255. Moreover, the court must view the evidence presented in light of the substantive evidentiary standards that apply in the case. *Id.* at 254-55. "Under the patent statutes, a patent enjoys a presumption of validity, which can be overcome only through clear and convincing evidence." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001) (citations omitted). Thus, "a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Id.*; *see also El v. Se. Pa. Transp. Auth.*, 479 F.3d 232, 238 (3d Cir. 2007) (where moving party will bear the burden of proof at trial, "it is inappropriate to grant summary judgment . . . unless a reasonable

juror would be compelled to find [the moving party's] way on the facts needed to rule in its favor on the law").

III. Discussion

AstraZeneca asserts that independent claims 1, 26, 42, and 52 of Teva's '502 patent are invalid under 35 U.S.C. § 102(g)(2). (AstraZeneca Mem. 14-18.) Under that provision,

> [a] person shall be entitled to a patent unless—
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> [. . .]
>
> before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Id. § 102(g)(2). Priority of invention under § 102(g)(2) thus "depends upon conception and reduction to practice." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). A patent will be invalid for prior invention under § 102(g)(2) if another inventor either reduced the invention to practice first, or conceived of the invention first and then exercised reasonable diligence in reducing the invention to practice, provided that the prior inventor did not abandon, suppress, or conceal the invention. *Mycogen Plant Science, Inc. v. Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001); *see also Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1381 (Fed. Cir. 2002). Where, as here, the priority of invention issue involves a comparison between an issued patent (Teva's '502 patent) and work performed by scientists (researchers at AstraZeneca), "it is . . . appropriate to place the focus of inquiry upon the specific claims of the [issued] patent[] as

representing the invention at issue." *Mycogen Plant Science*, 243 F.3d at 1332.[14]

"Conception is the formation, in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice." *Cooper*, 154 F.3d at 1327. "A conception must encompass all limitations of the claimed invention, and 'is complete only when the idea is so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.'" *Brown v. Barbacid*, 276 F.3d 1327, 1336 (Fed. Cir. 2002) (citations omitted). To establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the allegedly infringed patent; and (2) he determined that the invention would work for its intended purpose.[15]

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[14]Claim 1 of the Teva patent is representative:

What is claimed is:

1. A stabilized pharmaceutical composition for the treatment of dyslipidemia, comprising

> an active component consisting essentially of one or more compounds selected from the group consisting of (i) a*n HMG-CoA reductase inhibiting* ring-opened 7-substituted-3,5-dihydroxyheptafloic acid or a pharmaceutically acceptable acid salt thereof, and (ii) a*n HMG-CoA reductase inhibiting* ring-opened 7-substituted 3,5-dihydroxyheptenoic acid or a pharmaceutically acceptable acid salt thereof, and
>
> a stabilizing effective amount of at least one amido-group containing polymeric compound or at least one amino-group containing polymeric compound, or combination thereof, wherein said stabilized pharmaceutical composition does not contain a stabilizing effective amount of another stabilizer or a combination of other stabilizers.

[15] Alternatively, an inventor may rely on a constructive reduction to practice, which occurs when a patent application is filed. *Cooper*, 154 F.3d at 1327. Here, however, AstraZeneca seeks to establish priority of invention based on work performed before it filed either of its patent applications.

Mycogen Plant Science, 243 F.3d at 1332. In addition, "'[i]t is well-settled that conception and reduction to practice cannot be established nunc pro tunc. There must be contemporaneous recognition and appreciation *of the invention* represented by the [asserted patent claims].'" *Id.* at 1335 (quoting *Breen v. Henshaw*, 472 F.2d 1398, 1401 (C.C.P.A. 1973)) (first alteration in original); *see also Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1341 (Fed. Cir. 2001) ("[T]he date of the conception of a prior inventor's invention is the date the inventor first appreciated the fact of what he made."). "Priority, conception, and reduction to practice are questions of law which are based on subsidiary factual findings." *Cooper*, 154 F.3d at 1327.

A. Claims of the Parties

AstraZeneca argues that summary judgment is warranted because the undisputed evidence shows that it invented first. In particular, AstraZeneca argues that there is no dispute (1) that it made the same CRESTOR® product formulations that Teva accuses of infringement well before December 1, 1999, the earliest date by which Teva claims to have conceived of and reduced to practice the subject matter of the '502 patent,[16] and (2) that it has not "abandoned, suppressed, or concealed" these formulations. (AstraZeneca Mem. 1-2, 14-18.) AstraZeneca further argues that there is no dispute that the earlier-made CRESTOR® product formulations meet the limitations of the asserted claims of the '502 patent because AstraZeneca has conceded, for purposes of this motion, Teva's allegation that CRESTOR® infringes those claims. (*Id.* at 2,

[16] In its discovery responses, Teva stated that it conceived of and reduced to practice the invention claimed in the '502 patent "not later than December 1, 1999." (Elluru Decl., Ex. 3.) In its opposition to AstraZeneca's summary judgment motion, Teva asserts that its researchers conceived of the invention "[b]efore December 1999" (Teva Opp'n 4); however, Teva has not identified any date prior to December 1, 1999, by which the invention was conceived or submitted any evidence to support such a claim.

16-17.) Invoking the "century-old axiom of patent law . . . that a product which would literally infringe if later in time anticipates if earlier" (*id.* at 14 (citations and internal quotation marks omitted)), AstraZeneca argues that because it "made," *i.e.*, conceived of and reduced to practice, the allegedly infringing product in the United States before Teva conceived of or reduced to practice the subject matter of the '502 patent, AstraZeneca's earlier-developed product formulations anticipate the asserted patent claims under § 102(g)(2).

Teva does not dispute that AstraZeneca made the accused CRESTOR® product formulations before December 1, 1999. Rather, Teva contends that even if AstraZeneca created the exact infringing commercial formulation in mid 1999, AstraZeneca still cannot prove conception or reduction to practice of the invention claimed by Teva's '502 patent by that date because there is no evidence that AstraZeneca has ever appreciated that crospovidone, the amido-group containing polymeric compound included in CRESTOR®, contributes to the stability of the formulation. (Teva Opp'n 1, 14-16.) According to Teva, because the '502 patent "claims a formulation that achieves stability by the addition of a class of excipients that includes . . . crospovidone," AstraZeneca's failure to appreciate the stabilizing effect of crospovidone (even though crospovidone was included in its CRESTOR® formulations) is fatal to its claim of prior invention. (*Id.* at 15-16.)

B. Priority of Invention

1. Undisputed Evidence That AstraZeneca Made CRESTOR® First

As an initial matter, the court agrees with AstraZeneca that, based on the record before it, there is no genuine factual issue that AstraZeneca arrived at its allegedly infringing CRESTOR® product formulations—and made multi-thousand-unit batches of those formulations—before

Teva either conceived of or reduced to practice the subject matter of its '502 patent. Teva concedes that in mid 1999 AstraZeneca made a 10,000-unit batch of 2.5 mg rosuvastatin sales formulation tablets containing the same ingredients, in the same amounts, as the commercial 2.5 mg CRESTOR® tablet cores. (AstraZeneca Statement ¶¶ 35-36; Teva Resp. ¶¶ 35-36.) It is also undisputed that AstraZeneca made a 20,000-unit batch of 5 mg rosuvastatin sales formulation tablets in the summer of 1999, and a 160,000-unit batch of coated 2.5 mg rosuvastatin sales formulation tablets in the fall of 1999, both containing the same ingredients, in substantially identical amounts, as the corresponding commercial CRESTOR® products.[17] (*See* AstraZeneca Statement ¶¶ 38, 47; Teva Resp. ¶¶ 38, 47. *Compare* Creekmore Decl., Ex. D at AZ-EDPA-001314 to 001315 (batch records for summer 1999 batch) *and* Ex. F at AZ-EDPA-0026414 to 0026415 (batch records for fall 1999 batch), *with id.*, Ex. A at AZ-EDPA-0019433 (NDA).) Moreover, in his late summer 1999 presentation, Dr. Creekmore disclosed ingredients and amounts matching those contained in the commercial CRESTOR® tablet cores for all dosage strengths. (*See* AstraZeneca Statement ¶¶ 41-45; Teva Resp. ¶¶ 41-45.) Because Teva has

[17] As noted at nn.6-7 *supra*, the master formula pages for both the summer of 1999 and the fall of 1999 batches list the same ingredients, in the same amounts, as the corresponding commercial CRESTOR formulations. (*Compare* Creekmore Decl., Ex. D at AZ-EDPA-001314 (summer 1999 batch) *and* Ex. F at AZ-EDPA-0026414 (fall 1999 batch), *with id.*, Ex. A at AZ-EDPA-0019433 (NDA).) The weigh sheets for both batches show slight adjustments to the amount of two ingredients—rosuvastain calcium and microcrystalline cellulose—actually used in the batches. (*Compare* Creekmore Decl., Ex. D at AZ-EDPA-001315 (July 1999 batch) *and* Ex. F at AZ-EDPA-0026415 (October 1999 batch), *with id.*, Ex. A at AZ-EDPA-0019433 (NDA).) However, the weigh sheets and master formula pages themselves provide clear and convincing evidence that these minor adjustments were the result of a correction factor used to compensate for the amount of moisture present in the rosuvastatin calcium and a corresponding adjustment to the amount of microcrystalline cellulose in the formulation and no reasonable jury could decide otherwise. *See* nn.6-7, *supra*. Notably, Teva does not argue that these minor discrepancies are material to whether the rosuvastatin sales formulation tablets AstraZeneca made in summer and fall of 1999 are the same as the commercial CRESTOR® product.

identified no date prior to December 1, 1999, by which its conception or reduction to practice of the subject matter of the '502 patent had occurred, and submitted no such evidence, there is no genuine issue of material fact as to whether AstraZeneca arrived at the same CRESTOR® product formulations that Teva accuses of infringement—and made batches of those formulations—before Teva conceived of or reduced to practice the subject matter of the '502 patent. The record has established this point by clear and convincing undisputed evidence, which no reasonable jury could interpret otherwise.

2. AstraZeneca's Limited Concession of Infringement

The court also agrees with AstraZeneca that it may satisfy its burden to show that its earlier-made CRESTOR® products meet all the limitations of the asserted claims of Teva's '502 patent by conceding, for purposes of this summary judgment motion only, Teva's allegations of infringement. The Federal Circuit addressed a similar issue in *Evans Cooling Systems, Inc. v. General Motors Corp.*, 125 F.3d 1448, 1450 (Fed. Cir. 1997), a patent infringement action in which the defendant filed a motion for summary judgment asserting that the patent at issue was invalid for anticipation under 35 U.S.C. § 102(b)[18] because the allegedly infringing product had been offered for sale more than a year before the plaintiff had filed its patent application. Noting that the entire basis of the plaintiff's lawsuit was that the device that the defendant had offered for sale infringed the plaintiff's patent—which allegation the defendant had conceded for purposes of its summary judgment motion—the court held that no further showing of identity between the allegedly infringing product and the patented invention was required: "[a]lthough

[18] Section 102(b) provides, in relevant part, that a person shall not be entitled to a patent if "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States."

[defendant] bore the burden of proving that the [allegedly infringing product] embodied the patented invention or rendered it obvious for purposes of the summary judgment motion, this burden is met by [plaintiff's] allegation, forming the sole basis for the complaint that the [allegedly infringing product] infringes." *Evans Cooling Sys.*, 125 F.3d at 1451; *accord Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000) (same).

Although both *Evans Cooling Systems* and *Vanmoor* involved motions for summary judgment of invalidity based on the "on sale" bar of § 102(b), the court agrees with AstraZeneca that the same reasoning applies in the § 102(g) context. Indeed, at least one district court has so held, concluding that a defendant in a patent infringement action had met its burden to show the identity of the patented invention and the accused product based on the plaintiffs' assertion that the accused product infringed, which assertion the defendant had accepted for purposes of its motion for summary judgment of invalidity pursuant to § 102(g). *Benedict v. Gen. Motors Corp.*, 184 F. Supp. 2d 1197, 1200 (N.D. Fla. 2002), *appeal dismissed*, 42 F. App'x 466 (Fed. Cir. 2002); *cf. Bennett Regulator Guards, Inc. v. Canadian Meter Co., Inc.*, 184 F. App'x 977, 978 n.1 (Fed. Cir. 2006) (agreeing that "[w]hen the anticipatory reference is the accused product, the Defendant's burden [of showing that the anticipatory reference contains each and every claim element] is satisfied by the Plaintiff's infringement allegations in the Complaint that the accused product embodies the claimed invention" in a case in which the defendant raised a defense of invalidity under § 102(a)[19] as well as § 102(b)).

Teva objects that "[u]nlike § 102(g), which expressly requires consideration of the dates

[19] Under § 102(a), a person shall not be entitled to a patent if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent."

of *conception* and *reduction to practice* to show priority, § 102(b) provides for patentability unless 'the invention was *patented or described in a printed publication* . . . more than one year prior to the date of the application for patent in the United States.'" (Teva Opp'n 19 (quoting § 102(b)) (emphasis supplied by Teva).) Elsewhere in its opposition memorandum, Teva suggests because AstraZeneca has never appreciated that crospovidone contributes to the stability of its CRESTOR® product formulations, it cannot have "create[d] an embodiment that literally met all of the limitations of Teva's claims." (*See* Teva Opp'n 16 (stating that Dr. Creekmore believes that crospovidone *hinders* the stability of the formulation and suggesting that Creekmore "certainly did not create an embodiment that literally met all of the limitations of Teva's claims, or show that the invention would work for its intended purpose under the standard set forth by the Federal Circuit").) But whether AstraZeneca's CRESTOR® product formulations in fact meet all of the limitations of the asserted '502 patent claims and whether AstraZeneca appreciated this fact are separate inquiries. *See Mycogen Plant Science*, 243 F.3d at 1335-37 (concluding that "the portion of the reduction to practice test requiring that all limitations of the count be met ha[d] been satisfied" and addressing separately whether appellee appreciated the limitations of the allegedly infringed patent claims).

As in *Evans Cooling Systems*, *Vanmoor*, and *Benedict*, the entire basis of Teva's lawsuit is that AstraZeneca's CRESTOR® products infringe the asserted claims of the '502 patent. (Compl. ¶¶ 16, 18.) Thus, by conceding, for purposes of the instant summary judgment motion, Teva's allegation that CRESTOR® infringes, there is no genuine issue of material fact that AstraZeneca has met its burden to show by clear and convincing evidence with which a reasonable jury could not disagree that CRESTOR® meets all limitations of the asserted patent

claims.

3. Appreciation

As to Teva's argument that AstraZeneca has failed to prove prior conception or reduction to practice of the subject matter of the '502 patent because there is no evidence that its researchers appreciated the stabilizing effect of crospovidone on statin formulations, AstraZeneca agrees that its researchers lacked this specific appreciation. (*See* AstraZeneca Reply 2 (acknowledging that crospovidone "was included in the CRESTOR® formulations for its properties as a disintegrant").) Indeed, AstraZeneca notes in its reply brief that Dr. Creekmore "*disputes* Teva's contention about the stabilizing properties of povidone and [crospovidone]." (*Id.* (emphasis added).) AstraZeneca instead argues that even if Teva is correct about the stabilizing effect of crospovidone as a matter of science, it was not necessary for AstraZeneca to appreciate how, exactly, the allegedly infringing CRESTOR® product formulations achieved stability in order to establish priority of invention under § 102(g)(2). (*See id.* at 2-3.) Rather, it is enough that AstraZeneca appreciated that the CRESTOR® product formulations were in fact stable.[20] (*See id.* at 3-6.)

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[20] AstraZeneca has presented evidence that it appreciated that the rosuvastatin sales formulations were stable by late summer of 1999, when Dr. Creekmore made a presentation noting that "[c]oncurrent stability studies show product will have an acceptable shelf life." (Creekmore Decl. ¶¶ 18, 20 & Ex. E at AZ-EDPA-0041447.) Although Teva denies that Dr. Creekmore's presentation "evidences any understanding of the stabilizing effect of amido-group containing polymeric compounds, such as crospovidone, on statin-containing formulations," Teva does not dispute that AstraZeneca appreciated that its sales formulations were stable. (*See* Teva Resp. ¶ 46 (admitting that Creekmore's presentation contains the referenced statement).)

At oral argument, Teva suggested for the first time that there is a genuine factual issue as to whether the CRESTOR® product formulations were stable, as that term is used in the '502 patent. Teva asserts that while the patent defines the term "stabilized pharmaceutical composition" to mean that "after storage for six months at 40° C. and 75% relative humidity, no more than about 10%, preferably no more than about 5%, and more preferably, no more than

As noted, conception and reduction to practice require "'contemporaneous recognition and appreciation *of the invention* represented by [the asserted patent claims].'" *Mycogen Plant Science*, 243 F.3d at 1335 (citation omitted); *accord Rosco, Inc.*, 304 F.3d at 1381 (same); *see also Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1064 (Fed. Cir. 2005) (to establish priority of invention, there must be evidence not only that the inventor "actually first made the invention" but also that he "understood his creation to have the features that[] comprise the inventive subject matter at bar"). However, the inventor need not "establish that he recognized the invention in the same terms as those recited in the [claims]" as "[t]he invention is not the language of the claims but the subject matter thereby defined." *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974); *see also Mycogen Plant Science*, 243 F.3d at 1336 ("The reduction to practice test does not require *in haec verba* appreciation of each of the limitations of the count."). Rather, the inventor must establish that he recognized and appreciated "a compound corresponding to the compound defined by the [claims]." *Silvestri*, 496 F.2d at 599. Paragraph 12 of Teva's complaint defines the invention as follows: "[t]he '502 patent claims stabilized pharmaceutical compositions comprising statins for the treatment of dyslipidemia." AstraZeneca defined the invention by stating that Creekmore "appreciated the fact of what he made"; *i.e.*, a stable formulation containing rosuvastatin that could be manufactured commercially.

In support of its argument that appreciation of the stabilizing effect of crospovidone was

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about 1% by weight of the active component initially present in the composition degrades into the corresponding lactone" (Waldrop Decl., Ex. 1 ('502 patent) at col.3 l.65–col.4 l.3), AstraZeneca has not produced six-month stability data for its infringing CRESTOR® products. As set forth above, however, by conceding, for purposes of this motion, Teva's allegation that CRESTOR® infringes, AstraZeneca has met its burden to show that CRESTOR® meets all limitations of the asserted patent claims, including that CRESTOR® is a "stabilized" (or, for purposes of independent claims 42 and 52, "stable") pharmaceutical composition.

not required, AstraZeneca relies on a series of cases in which the Federal Circuit has held that "'a reference may anticipate even when the relevant properties of the thing disclosed were not appreciated at the time.'" (*See* AstraZeneca Reply 2-3 (quoting *Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 471 F.3d 1363, 1367 (Fed. Cir. 2006).) *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775 (Fed. Cir. 1985), cited by AstraZeneca, has been described as the "classic case" on this point. *See Abbott Labs.*, 471 F.3d at 1367. In that case, inventors sought to patent a titanium alloy consisting of certain specified ingredients in specified proportions and "characterized by good corrosion resistance in hot brine environments." 778 F.2d at 776. A prior art reference—an article in a Russian publication—disclosed, through data points on graphs, alloys falling within the scope of the patent claims, but contained no disclosure of corrosion-resistant properties of any of the alloys. *Id.* at 777. Although the patent applicants, by their disclosure of such corrosion resistance, "had discovered or invented and disclosed knowledge which [was] not to be found in the reference," the court nevertheless held that the Russian article anticipated the patent claims. *Id.* at 780-82.

In deciding whether the claimed alloys were patentable, the critical question was whether "what [was] sought to be patented, as determined by the claims, [was] new." *Id.* at 780. Because the Russian article disclosed a titanium base alloy falling squarely within the ranges of the patent claims, the court concluded that the claimed alloys were not new, finding it "immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties":

> Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the

composition of the alloy without losing such properties.

Id. at 781-82.

Applying this principle—that "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer"[21]—the Federal Circuit has held invalid for anticipation numerous patents claiming what amount to newly discovered properties of prior art compositions, where the missing characteristic was necessarily present, or inherent, in the prior art, even though there was no recognition of the missing characteristic in the prior art.[22] Based

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[21] *Atlas Powder Co. v. IRECO Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

[22] *See, e.g.*, *Abbott Labs.*, 471 F.3d at 1368-69 (patent disclosing a composition of water-saturated sevoflurane anticipated later patent disclosing a composition comprising sevoflurane mixed with water or another Lewis acid inhibitor in an amount effective to prevent degradation by a Lewis acid, even though earlier patent did not teach that the mixture would prevent sevoflurane from degrading in the presence of Lewis acids); *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349-50 (Fed. Cir. 2001) (patents claiming a structure for a metallic fuse for semi-conductor chips and a method for fabricating and blowing such a fuse, both of which recited a theoretical explosive mechanism for blowing the fuse, were anticipated by earlier patents that disclosed the same fuse structure but not the explosive mechanism where explosive mechanism was "a scientific explanation for the process of blowing the claimed fuse structure" that was inherent in fuses of the same structure); *Atlas Powder Co.*, 190 F.3d at 1348-49 (patents disclosing blasting compositions were anticipated by earlier patents disclosing compositions containing the same ingredients in overlapping amounts, notwithstanding that earlier patents lacked limitation that there be "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree": "[b]ecause 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of Dr. Clay's invention—that air may act as the sole sensitizer of the explosive composition"); *accord In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1371-73 (Fed. Cir. 2007) (patent reciting a process for making a pharmaceutical formulation composed of an omeprazole core, a water soluble separating layer, and an enteric coating layer, wherein the separating layer was created by causing an *in situ* reaction involving the other two layers, was anticipated by an earlier patent application that contained all elements of the later patent except the *in situ* formation of the separating layer—and that expressly disavowed a subcoating—where the *in situ* formation was inherent); *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 633 (Fed. Cir. 1987) (patent disclosing a process for making certain known urea-sulfuric acid liquid fertilizer products, in which a

on this case law, AstraZeneca argues in essence that if Teva is correct about the stabilizing effect of crospovidone, then the earlier-made CRESTOR® product formulations possess that property inherently, such that AstraZeneca was not required to have appreciated the property in order to have conceived of and reduced to practice the subject matter of the asserted '502 patent claims.

At oral argument, Teva argued that the cases on which AstraZeneca relies are inapposite because they involved allegations of invalidity under § 102(b), not § 102(g), and the Federal Circuit thus had no need to address the issues of conception, reduction to practice, and appreciation.[23]

Even in the § 102(g) context, however, the Federal Circuit has recognized that a prior inventor need not always have appreciated every feature recited in a patent claim in order to have conceived of or reduced to practice the claimed invention. For example, in *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1434-36 (Fed. Cir. 1988), the Federal Circuit held that a defendant in an infringement action could meet its burden to show invalidity under § 102(g) by proving that its researchers' earlier-made products possessed certain property limitations of the asserted patent claims, without also showing that the researchers were aware that their products possessed the properties. The patent claims at issue in the case related to various copolymers, and as to four of the six claims at issue, the plaintiff had conceded that the defendant's researchers had made the claimed copolymers before the plaintiff had. *Id.* at 1434 & n.3. The remaining two claims included certain property limitations not present in the other four,

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previously made batch of liquid fertilizer known as a "heel" served as a "heat sink" to absorb the heat of the reaction, was anticipated by an earlier patent disclosing the same process, even though earlier patent did not recognize that the heel functioned as a heat sink).

[23]Teva cited no cases to support this proposition.

and as to those claims, the court remanded the case for a determination "whether the claimed copolymer, as defined in part by various property parameters, [was] new." *Id.* at 1434-36. The court observed that as the one challenging the validity, the defendant would have the burden on remand to prove that the property limitations were possessed by its researchers' products, but stated that in meeting that burden, the defendant "*need not prove awareness by [its researchers] that their products possessed the properties*." *Id.* at 1436 (emphasis added). Moreover, in the interference context, the Federal Circuit also has held that a prior inventor need not have appreciated those "inherent properties" of the count that "add nothing to the count beyond the other recited limitations and are not material to the patentability of the invention." *Griffin v. Bertina*, 285 F.3d 1029, 1034 (Fed. Cir. 2002).[24]

[24]Teva argues that appreciation of each claim limitation is required, citing *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F.3d 1052 (Fed. Cir. 2005), but that case is distinguishable. The invention at issue in *Invitrogen* was an enzyme (reverse transcriptase or "RT") that had been genetically modified in ways that made it useful for efficiently cloning DNA. Specifically, the invention was genetically engineered RT that had DNA polymerase activity but lacked RNase H activity. *Id.* at 1062. Invitrogen had reduced the invention to practice by January 1987, but Clontech claimed an earlier date of conception based on work by Dr. Stephen Goff, who in 1984 had prepared some 100 random mutations in the MMLV gene for RT, two of which produced enzymes that were later determined to possess the desired properties. *Id.* at 1058-59. Goff's mutants were not shown to lack RNase H activity, however, until after Invitrogen's reduction to practice date. *Id.* at 1059. The district court granted partial summary judgment for Clontech, finding that Goff had conceived of the invention in 1984, when he produced the two mutants, or in 1986, when he sequenced the mutants. *Id.* at 1061-62. The Federal Circuit reversed, rejecting the argument that Goff had set out to create RT lacking RNase H activity when he prepared his panel of mutant genes in 1984, and noting the record instead suggested that the action "fit[] squarely within the unrecognized, accidental duplication cases," given the general nature of Goff's research and the lack of knowledge at the time whether it was possible to make RT lacking RNase H activity but retaining DNA polymerase activity. *Id.* at 1066. In contrast, the evidence in this case is undisputed that AstraZeneca set out to produce a stable pharmaceutical composition containing a statin that could be produced commercially. AstraZeneca thus appreciated that its creation possessed the relevant inventive feature—stability—even if its understanding of how its creation achieved stability was incorrect.

In view of the fact that the earlier-made CRESTOR® product formulations have been shown to meet all limitations of the asserted '502 patent claims (by virtue of AstraZeneca's limited concession of infringement), Teva's discovery that crospovidone contributes to the stability of the formulations resembles the sort of scientific explanation for a prior art composition's functioning that the Federal Circuit has found to be an inherent property of the prior art in other cases. *See Abbott Labs.*, 471 F.3d at 1368 (property of resistance to Lewis acid degradation resulted from combination of sevoflurane and water; therefore, property was inherent in prior art's disclosure of water-saturated sevoflurane); *EMI Group N. Am., Inc.*, 268 F.3d at 1350 (scientific mechanism of how metallic fuses in semi-conductor chips sever is inherent in fuses with the same structure); *Atlas Powder Co.*, 190 F.3d at 1349 (once interstitial and porous air were shown to be inherent elements of prior art blasting compositions, "the assertion that air may act as a sole sensitizer amounts to no more than a claim to the discovery of an inherent property of the prior art").[25] The discovery of this inherent property does not make the pharmaceutical compositions claimed by Teva—which AstraZeneca undisputedly made first—new. *See, e.g.*, *Abbott Labs*, 471 F.3d at 1368 ("The general principle that a newly-discovered property of the prior art cannot support a patent on that same art is not avoided if the patentee explicitly claims that property."); *E.I. du Pont de Nemours & Co.*, 849 F.2d at 1436 (claimed copolymer defined in part by property parameters would not be new if property limitations were possessed by putative prior inventor's products, even if prior inventor was unaware of that fact). Accordingly, the court concludes as a matter of law that an appreciation of

[25] Teva has not disputed AstraZeneca's assertion in its reply brief that to the extent that crospovidone stabilizes, it does so inherently. (*See* AstraZeneca Reply 2.)

the stabilizing effect of crospovidone by AstraZeneca, as opposed to its appreciation of the stabilization of its overall pharmaceutical composition that contained crospovidone, was not required.[26]

Dr. Creekmore's recognition that the rosuvastatin sales formulations were stable and sufficiently finalized to proceed commercially establishes that Dr. Creekmore appreciated "the fact of his invention" no later than late summer of 1999, months before Teva's alleged date of conception. *See Dow Chem. Co.*, 267 F.3d at 1341. In *Dow*, also a § 102(g) case, the Federal Circuit reaffirmed its prior decisions that a prior inventor is not required to establish that he recognized the invention in the same terms as those recited in the count. The invention is not the language of the count but the subject matter thereby defined. The prior inventor must establish that he recognized and appreciated the new form. The court then concluded that "the cases establish that the date of the conception of a prior inventor's invention is the date the inventor first appreciated the fact of what he made. . . . It is enough that the [prior inventor] appreciated the fact of [his] invention." *Dow* at 1341. Creekmore appreciated "the fact of what he made," *i.e.*, a stable formulation containing rosuvastatin that could be manufactured commercially. As in *Dow*, he "clearly recognized and appreciated the existence of [a] new . . . product." *Id*.

AstraZeneca has presented clear, convincing, and undisputed evidence on the basis of which a reasonable jury would be compelled to find that before December 1, 1999, AstraZeneca had arrived at its CRESTOR® product formulations for all dosage strengths, had made; *i.e.*,

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[26] Because the court concludes that AstraZeneca need not show that it appreciated the stabilizing effect of crospovidone in its CRESTOR® product formulations, the court need not address Teva's alternative argument that AstraZeneca has failed to produce corroborating evidence that it had such an appreciation. (*See* Teva Opp'n 16-18.)

conceived and reduced practice, multi-thousand-unit batches of the 2.5 mg and 5 mg tablets, and had concluded, based on stability studies, that the product formulations would have an acceptable shelf life and would therefore work for their intended purpose. On the basis of this clear, convincing, and undisputed evidence—and AstraZeneca's concession of infringement for purposes of this motion, by which AstraZeneca has satisfied its burden to show that the CRESTOR® product formulations meet all limitations of the asserted '502 patent claims—there is no genuine issue of material fact and the court concludes as a matter of law that AstraZeneca conceived of and reduced to practice the subject matter of those claims before Teva did.

C. Abandonment, Concealment, or Suppression

It is also clear that AstraZeneca did not abandon, suppress, or conceal its earlier-developed CRESTOR® formulations. The requirement of § 102(g) that the prior inventor must not have "abandoned, suppressed, or concealed" his invention "encourages prompt public disclosure of an invention by penalizing the unexcused delay or failure of a first inventor to share the 'benefit of the knowledge of [the] invention' with the public after the invention has been completed." *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995) (quoting *Paulik v. Rizkalla*, 760 F.2d 1270, 1280 (Fed. Cir. 1985) (Rich, J., concurring)) (alteration in original). "One way a prior inventor may avoid the disqualifying effect of § 102(g) is by promptly filing a patent application claiming the invention." *Id.* Another is by showing that the prior inventor "engaged in reasonable efforts to bring the invention to market." *Id.* at 762; *see also Dow Chem. Co.*, 267 F.3d at 1343. Here, AstraZeneca has done both.

Following its manufacture of batches of 2.5 mg and 5 mg rosuvastatin sales formulation tablets from mid 1999 to the fall of 1999, AstraZeneca filed patent applications covering the

CRESTOR® formulations in Great Britain in January of 2000 and in the United States on August 4, 2000. (Creekmore Decl. ¶¶ 22-23.) The Great Britain patent application was apparently terminated in January 2001 (Jones Decl. ¶ 6 & Ex. I), while the United States application was ultimately issued as the '460 patent in November 2001 (Creekmore Decl. ¶ 23; Elluru Decl., Ex. 2). In addition to filing these patent applications, AstraZeneca also filed an NDA for CRESTOR® in June 2001, and began marketing CRESTOR® commercially in the United States after receiving FDA approval in August 2003. (*See id.*, Ex. 8; Sloan Decl. ¶ 6.) Teva has produced no evidence disputing these facts. These activities are sufficient to show by clear and convincing evidence that AstraZeneca did not abandon, suppress, or conceal its invention, and a reasonable jury could not find otherwise. *See Dow Chem. Co.*, 267 F.3d at 1343 (inventor did not suppress or conceal invention despite thirty-month delay between first making the invention and selling it where undisputed evidence showed that inventor "actively and continuously took steps towards the commercialization of the [invention]" during that time); *Checkpoint Sys., Inc.*, 54 F.3d at 762 & n.6 (four-year delay in introducing product to the marketplace was not unreasonable where prior inventor was "diligent in working toward commercializing the [invention]").

Teva argues that AstraZeneca's British patent application and '460 patent support, rather than negate, a finding of suppression or concealment here because those applications do not disclose any appreciation that crospovidone contributed to the stability of the formulation. (Teva Opp'n 21.) Agreed. As set forth above, however, the court has concluded that AstraZeneca was not required to have such an appreciation in order to establish priority of invention. Accordingly, AstraZeneca need not have disclosed such appreciation in its patent filings.

IV. Conclusion

AstraZeneca has presented clear, convincing, and undisputed evidence with which a reasonable jury could not disagree that it conceived and reduced to practice an embodiment meeting the limitations of the asserted claims of Teva's '502 patent before Teva did, and that it did not abandon, suppress, or conceal its invention. There is no genuine issue of a material fact. Accordingly, the court will grant AstraZeneca's motion for summary judgment of invalidity under § 102(g)(2). An appropriate order accompanies this memorandum.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

TEVA PHARMACEUTICAL INDUSTRIES LTD.,	:	CIVIL ACTION
Plaintiff	:	
	:	
vs.	:	
	:	
ASTRAZENECA PHARMACEUTICALS LP, *et al*.,	:	
	:	
Defendants.	:	NO. 08cv4786

ORDER

AND NOW, this _____ day of October, 2010, upon consideration of the motion for summary judgment of defendants AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc. (collectively "AstraZeneca") (docket no. 54), the opposition of plaintiff Teva Pharmaceutical Industries Ltd. ("Teva") (docket no. 78), and AstraZeneca's reply thereto (docket no. 81), **IT IS HEREBY ORDERED** that

(1) the motion is **GRANTED**;

(2) independent claims 1, 26, 42, and 52 of U.S. Patent No. RE39,502 are invalid pursuant to 35 U.S.C. § 102(g)(2);

(3) **JUDGMENT** is entered in favor of AstraZeneca Pharmaceuticals LP and IPR Pharmaceuticals, Inc. and against Teva Pharmaceutical Industries Ltd.; and

(4) the Clerk shall close this case for statistical purposes.

s/William H. Yohn Jr.
William H. Yohn Jr., Judge